IN THE UNITED STATES PATENT AND TRADEMARK OFFICE CEIVED

FEB 0 4 2002

In re application of: Johnson et al.

Application No. 09/890,806

Filed: November 16, 2001

For: INHIBITION OF THE MHC CLASS II ANTIGEN PRESENTATION PATHWAY AND PRESENTATION TO

CD4+ CELLS

Examiner:

Date: January 7, 2002

Art Unit: 1645

TECH CENTER 1600/2900

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service on January 7, 2002 as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 2023 1.

Tanya M. Harding, Ph.D Attorney for Applicant

PURSUANT TO 37 C.F.R. § 1.97(b)(3)

COMMISSIONER FOR PATENTS WASHINGTON, DC 20231

Sir:

Listed on the accompanying form PTO-1449 and enclosed herewith are several English-language documents. Applicants respectfully request that these documents be listed as references cited on the issued patent.

Applicants filed this Information Disclosure Statement ("IDS") before the mailing date of a first Office action on the merits. As a result, no fee should be required to file this IDS. However, if the Patent Office determines that a fee is required for Applicants to file this Information Disclosure Statement, please charge any such fees, or credit overpayment, to Deposit Account No. 02-4550. A duplicate copy of this Information Disclosure Statement is enclosed.

Respectfully submitted,

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Tanya M. Harding, Ph.D. Registration No. 42,630 FORMATION DISCLOSURE STATEMENT

BY APPLICANT

Docket: 899-59399

App: 09/890,806 4 20

Applicant: Johnson et al.

Filed: August 1, 2001 | Art Unit: 1645

U.S. PATENT DOCUMENTS

Init.*	Number	Date	Name	Class	Sub	Filed
	5,202,426	Apr 13, 1993	Strumwasser et al.			
	5,529,774	Jun 25, 1996	Barba et al.			
	5,720,957	Feb 24, 1998	Jones et al.			
	5,750,398	May 12, 1998	Johnson et al.			
	5,843,458	Dec 1, 1998	Jones			
	5,908,780	June 1, 1999	Jones			

FOREIGN PATENT DOCUMENTS

Init.*	Number	Date	Country	Class	Sub	
	 WO 97/32605	Sep 12, 1997	PCT			

OTHER DOCUMENTS

Init.*	Citation	
	-	Balashov <i>et al</i> , "Increased interleukin 12 production in progressive multiple sclerosis: Induction by activated CD4 ⁺ T cells via CD40 ligand," <i>Proc. Natl. Acad. Sci. USA</i> 94:599-603, January 1997
		Basta et al., "Identification of an interferon- γ response region 5' of the human histocompatibility leukocyte antigen DR α chain gene which is active in human glioblastoma multiform lines," J. Immunol. 138(4):1275-1280, February 15, 1987
		Batchelor et al., "Helper T-Lymphocyte Precursor Frequencies Predict Risks of Graft-Versus-Host Disease in Bone Marrow Transplantation," <i>Transplant. Proc.</i> 25(1):1237-1238, 1993
		Beersma et al., "Human Cytomegalovirus Down-Regulates HLA Class I Expression by Reducing the Stability of Class I H Chains," J. Immunol. 151(9):4455-4464, November 1, 1993

EXAMINER:	DATE
*Examiner: Initial if considered, whether or not in co	onformance with MPEP 609; draw line through cite

if not in conformance and not considered. Send copy.

0/2	Docket: 899-59399	App: 09/1990, 806 B 0 4 20	
STATEMENT	Applicant: Johnson et a	al. STER 1600	
BY APPLICANT	Filed: August 1, 2001	Art Unit: 1645	
nit.*	Citation		
immunodominant minor 1102, April 15, 1994	esets involved in lethal graft-ver histocompatibility antigens,"	Transplantation 57(7):1095-	
	QB1 Polymorphism Determine luced Arthritis in Transgenic M ember 1997	The state of the s	
depleting anti-CD4 antib	ntation tolerance induced by an body depends on CD4 ⁺ T cell response," <i>Eur. J. Immunol.</i> 25:2	egulation during the	
1 I	f E4 in Eliciting CD4 T-Cell ar ivered to Murine and Nonhum 998	_	
Myosin-B13 Trypanosor	oimmunity in Chagas Disease: ma cruzi Protein Crossreactive agas Cardiomyopathy Patient,	T Cell Clones in Heart	

_	L:I
	Bushell <i>et al.</i> , "Transplantation tolerance induced by antigen pretreatment and depleting anti-CD4 antibody depends on CD4 ⁺ T cell regulation during the induction phase of the response," <i>Eur. J. Immunol.</i> 25:2643-2649, 1995
	Chirmule et al., "Role of E4 in Eliciting CD4 T-Cell and B-Cell Responses to Adenovirus Vectors Delivered to Murine and Nonhuman Primate Lungs," J. Virol. 72(7):6138-6145, July 1998
	Cunha-Neto et al., "Autoimmunity in Chagas Disease: Identification of Cardiac Myosin-B13 Trypanosoma cruzi Protein Crossreactive T Cell Clones in Heart Lesions of a Chronic Chagas Cardiomyopathy Patient," J. Clin. Invest. 98(8):1709-1712, October 1996
	DeMatteo et al., "Immunologic barriers to hepatic adenoviral gene therapy for transplantation," Transplantation 63(2):315-319, January 27, 1997
	Fleury et al., "Mutational Analysis of the Interaction between CD4 and Class II MHC: Class II Antigens Contact CD4 on a Surface Opposite the gp120-Binding Site," Cell 66:1037-1049, September 6, 1991
	Gahéry-Ségard et al., "Phase I Trial of Recombinant Adenovirus Gene Transfer in Lung Cancer: Longitudinal Study of the Immune Responses to Transgene and Viral Products," J. Clin. Invest. 100(9):2218-2226, November 1997
	Goldsmith et al., "Infected Cell Protein (ICP)47 Enhances Herpes Simplex Virus Neurovirulence by Blocking the CD8 ⁺ T Cell Response," J. Exp. Med. 187(3):341-348, February 2, 1998
	González et al., "CD4 [†] cells determine the ability of spleen cells from F ₁ hybrid mice to induce neonatal tolerance to alloantigens and autoimmunity in parental mice," Eur. J. Immunol. 25:1760-1764, 1995

EXAMINER:	DATE			
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite				
if not in conformance and not considered. Send copy.				



FORMATION DISCLOSURE STATEMENT

BY APPLICANT

Docket: 899-59399 | App: 09/890,806

Applicant: Johnson et al.

Filed: August 1, 2001

Art Unit: 1645

Init.*	Citation
	Gossen <i>et al.</i> , "Tight control of gene expression in mammalian cells by tetracycline-responsive promoters," <i>Proc. Natl. Acad. Sci. USA</i> 89:5547-551, June 1992
	Haskins and Wegmann, "Diabetogenic T-Cell Clones," <i>Diabetes</i> 45:1299-1305, October 1996
	Heath et al., "Protection Against Graft-Versus-Host Disease by Large Doses of Donor CD4 ⁺ T Cells: A Novel Approach to Bone Marrow Transplantation," <i>Transplant. Proc.</i> 25(1):1222-1224, February 1993
	Hemmer et al., "Cytokine Phenotype of Human Autoreactive T Cell Clones Specific for the Immunodominant Myelin Basic Protein Peptide (83-99)," J. Neuro. Res. 45:852-862, 1996
	Hill et al., "Herpes simplex virus turns off the TAP to evade host immunity," Nature 375:411-415, June 1, 1995
	Hitt et al., "Techniques for Human Adenovirus Vector Construction and Characterization," Meth. Mol. Gen. 7:13-30, 1995
	Jones et al., "Multiple Independent Loci within the Human Cytomegalovirus Unique Short Region Down-Regulate Expression of Major Histocompatibility Complex Class I Heavy Chains," J. Virol. 69(8):4830-4841, August 1995
	Korngold, "Lethal graft-versus-host disease in mice directed to multiple minor histocompatibility antigens: features of CD8 + and CD4 + T cell responses," <i>Bone Marrow Transplant.</i> 9:355-364, 1992
	Krieger et al., "Prolongation of Cardiac Graft Survival with Anti-CD4Ig Plus hCTLA4Ig in Primates," J. Surg. Res. 76:174-178, 1998
	Kusugami et al., "Loss of Interleukin-2Producing Intestinal CD4+ T Cells in Inflammatory Bowel Disease," Gastroenterology 101(6):1594-1605, 1991

	DATE			
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite				
if not in conformance and not considered. Send copy.				

THE	ORMATION DISCLOSURE STATEMENT
	BY APPLICANT

Docket: 899-59399 | App: 09/890,806

Applicant: Johnson et al.

PEMARK OFFICE	
Init.*	Citation
	Lenschow et al., "Long-Term Survival of Xenogeneic Pancreatic Islet Grafts Induced by CTLA41g," Science 257:789-792, 7 August 1992
	Letterio et al., "Autoimmunity Associated with TGF-\beta1-Deficiency in Mice Is Dependent on HMC Class II Antigen Expression," J. Clin. Invest. 98(9):2109-2119, November 1996
	Linsley et al., "Immunosuppression in Vivo by a Soluble Form of the CTLA-4 T Cell Activation Molecule," Science 257:792-795, 7 August 1992
	Lohse et al., "Lack of Requirement for CD8 ⁺ Cells in Recovery from and Resistance to Experimental Autoimmune Encephalomyelitis," J. Autoimmun. 8:395-404, 1995
	Martens et al., "Expansion of unusual CD4+ T cells in sever rheumatoid arthritis," Arthritis & Rheumatism 40(6):1106-1114, June 1997
-	Massie et al., "Inducible Overexpression of a Toxic Protein by an Adenovirus Vector with a Tetracycline-Regulatable Expression Cassette," J. Virol. 72(3):2289-2296, March 1998
	McKnight et al., "Costimulator Dependence of Lymphokine Secretion By Naïve and Activated CD4 ⁺ T Lymphocytes From TCR Transgenic Mice," J. Immunol. 152:5220-5225, 1994
-	Meinl et al., "Encephalitogenic Potential of Myelin Basic Protein-Specific T Cells Isolated from Normal Rhesus Macaques," Amer. J. Pathol. 150(2):445-453, February 1997
	Mosyak et al., "The Structure of HLA-DM, the Peptide Exchange Catalyst that Loads Antigen onto Class II MHC Molecules during Antigen Presentation," Immunity 9:377-383, September 1998
-	Murphy et al., "B7 and Interleukin 12 Cooperate for Proliferation and Interferon γ Production by Mouse T Helper Clones That are Unresponsive to B7 Costimulation," J. Exp. Med. 180:223-231, July 1994

EXAMINER:	DATE			
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite				
if not in conformance and not considered. Send copy.				

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BY APPLICANT		Filed: August 1, 2001	App: 09/890,8 RECE
nit.*		Citation	
		n of obesity and diabetes in ge c. Natl. Acad. Sci. USA 93:148	-
		Analysis of the Binding Site I use 6-Phosphate Receptor," J. 199	
	**	pendent adenovirus vector syscision of the viral packaging s 0, November 1996	-
	1 4	intratracheal instillations of no conses and IFN-gamma produc	
	1 7	d Numbers of <i>in vivo</i> Activated endent Diabetes Mellitus," <i>J.</i>	
		ransfer of Diabetesin the NOD Requirements for CD3 T-Cell	
	Influenced More by Proce	on of the Goodpasture Autoant essing Constraints Than by HI em. 273(19):11440-11447, Ma	LA Class II Peptide Binding
	Platt, "Xenotransplanting Medicine 3(1):26-27, Janu	hepatocytes: The triumph of uary 1997	a cup half full," Nature
	in Renal Allograft Recipie	Monoclonal Antibody Therap ents-CD4 ⁺ T Cells Play an Ess oc. 27(1):859-862, February	•
	1 7	ent and Characterization of a Nexperimental Autoimmune Uve 60, 1996	

EXAMINER:	DATE			
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite				
if not in conformance and not considered. Send copy.				

N	FORMATION DISCLOSURE STATEMENT
7	STATEMENT

BY APPLICANT

Docket: 899-59399 | App: 09/890,806

Applicant: Johnson et al.

Trit *		Citation
Init.*		Citation
	-	Rudolph et al., "Gut-homing CD4 ⁺ T cell receptor $\alpha\beta^+$ T cells in the pathogenesis of murine inflammatory bowel disease," Eur. J. Immunol. 24:2803-2812, 1994
	¢	Sadlack <i>et al.</i> , "Generalized autoimmune disease in interleukin-2-deficient mice is triggered by an uncontrolled activation and proliferation of CD4+ T cells," <i>Eur. J. Immunol.</i> 25:3053-3059, 1995
	•	Sanderson et al., "Association Between HLA-DM and HLA-DR In Vivo," Immunity 4:87-96, January 1996
	,	Tak et al., "Reduction of synovial inflammation after anti-CD4 monoclonal antibody treatment in early rheumatoid arthritis," Arthritis & Rheumatism 38(10):1457-1465, October 1995
	-	Tary-Lehmann <i>et al.</i> , "Induction of graft versus host-associated immunodeficience by CD4+ T Cell Clones," <i>J. Immunol.</i> 145(7):2092-2098, October 1, 1990
		Thivolet <i>et al.</i> , "CD8 ⁺ T cell homing to the pancreas in the nonobese diabetic mouse is CD4 ⁺ T cell-dependent," <i>J. Immunol.</i> 146(1):85-88, January 1, 1991
	-	Thorsby and Røningen, "Role of HLA Genes in Predisposition to Develop Insulir dependent Diabetes Mellitus," <i>Annals of Med.</i> 24:523-531, 1992
	,	Tomazin et al., "Cytomegalovirus US2 destroys two components of the MHC class II pathway, preventing recognition by CD4 ⁺ T cells," <i>Nature Med.</i> 5(9):1039 1043, September 1999
		Toyosaki et al., "Recognition of rheumatoid arthritis synovial antigen by CD4+, CD8- T cell clones established form rheumatoid arthritis joints," Arthritis * Rheumatism 41(1):92-100, January 1998
	-	Tsuji et al., "Requirement of CD4 T Cells for Skin Graft Rejection Against Thymus Leukemia (TL) Antigen and Multiple Epitopes on the TL Molecule Recognized by CD4 T Cells," J. Immunol. 159:159-166, 1997

*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite	EXAMINER:	DATE
if not in conformance and not considered. Send conv		

NF(DRMATION DISCLOSURE
n	STATEMENT

BY APPLICANT

Docket: 899-59399 App: 09/890,806

Applicant: Johnson et al.

	
Citation	
	Van Ginkel et al., "Adenoviral Gene Delivery Elicits Distinct Pulmonary-Associated T Helper Cell Responses to the Vector and to Its Transgene," J. Immunol. 159:685-693, 1997
_	VanBuskirk et al., "Acute rejection of cardiac allografts by noncytolytic CD4 ⁺ T cell populations," Transplantation 62(2):300-302, July 27, 1996
	Vergelli et al., "Human Autoreactive CD4 ⁺ T Cell Clones Use Perforin- or Fas/Fas Ligand-Mediated Pathways for Target Cell Lysis," J. Immunol. 158:2756-2761, 1997
-	Weimer et al., "Pretransplant CD4 helper function and interleukin 10 response predict risk of acute kidney graft rejection," Transplantation 62(11):1606-1614, December 15, 1996
-	Weston et al., "Sequence of the short unique region, short repeats, and part of the long repeats of human Cytomegalovirus," J. Mol. Biol. 192:177-208, 1986
,	Wiertz et al., "The Human Cytomegalovirus US11 Gene Product Dislocates MHC Class I Heavy Chains from the Endoplasmic Reticulum to the Cytosol," Cell 84:769-779, March 8, 1996
	Wiertz et al., "Sec61-mediated transfer of a membrane protein from the endoplasmic reticulum to the proteasome for destruction," <i>Nature</i> 384:432-438, December 5, 1996
	Wubbolts et al., "MHC class II molecules: transport pathways for antigen presentation," Trends Cell Biology 7:115-118, March 1997
	Yang et al., "Cellular immunity to viral antigens limits E1-deleted adenoviruses for gene therapy," Proc. Natl. Acad. Sci. USA 91:4407-4411, May 1994
-	Yang et al., "Immunology of gene therapy with adenoviral vectors in mouse skeletal muscle," Human Mol. Gen. 5(11):1703-1712, 1996

EXAMINER:	DATE			
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite				
if not in conformance and not considered. Send copy.				

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BY APPLICANT

Docket: 899-59399 App: 09/890,806

Applicant: Johnson et al.

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	Citation	
•	Yang et al., "Role of Viral Antigens in Destructive Cellular Immune Responses to Adenovirus Vector-Transduced Cells in Mouse Lungs," J. Virol. 70(10):7209-7212, October 1996	
·	Yang et al., "Transient Subversion of CD40 Ligand Function Diminishes Immune Responses to Adenovirus Vectors in Mouse Liver and Lung Tissues," J. Virol. 70(9):6370-6377, September 1996	
•	York et al., "A Cytosolic Herpes Simplex Virus Protein Inhibits Antigen Presentation to CD8 ⁺ T Lymphocytes," Cell 77:525-535, May 20, 1994	
•	Zabner et al., "Adenovirus-Mediated Gene Transfer Transiently Corrects the Chloride Transport Defect in Nasal Epithelia of Patients with Cystic Fibrosis," Cell 75:207-216, October 22, 1993	
	Zelenika et al., "Rejection of H-Y Disparate Skin Grafts by Monospecific CD4 ⁺ Th1 and Th2 Cells: No Requirement for CD8 ⁺ T Cells or B Cells," J. Immunol. 161:1868-1874, 1998	
	GenBank Accession No. P29241, ADP-Ribosyl Cyclase Precursor, December 1, 1992	
•	GenBank Accession No. P09713, Hypothetical Protein HQLF2, March 1, 1989	
-	GenBank Accession No. QQBEC5, HQLF2 protein precursor – human cytomegalovirus (strain AD169), September 30, 1989	

EXAMINER:	DATE		
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite			
if not in conformance and not considered. Send copy.			